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Re-evaluation Decision RVD2012-05

Fluazifop-P-butyl

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Re-evaluation Decision

After a re-evaluation of the herbicide fluazifop-P-butyl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing fluazifop-P-butyl for sale and use in Canada.

An evaluation of available scientific information found that products containing fluazifop-P-butyl do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of fluazifop-P-butyl uses, new mitigation measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of fluazifop-P-butyl was first presented in Proposed Re-evaluation Decision PRVD2011-11, *Fluazifop-P-butyl*, a consultation document[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of fluazifop-P-butyl as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process did not result in substantial changes to the proposed regulatory decision as described in PRVD2011-11. Appendix I summarizes the comments and provides the PMRA's response. To comply with this decision, registrants of products containing fluazifop-P-butyl will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Fluazifop-P-butyl has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency Reregistration Eligibility Decision documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate mitigation measures for Canadian uses of fluazifop-P-butyl. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The United States Environmental Protection Agency conducted human health risk assessments for fluazifop-P-butyl, published in the 2005 Tolerance Reassessment Eligibility Document and the 2008 Human Health Risk Assessment.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-11, *Fluazifop-P-butyl*.

What Is Fluazifop-P-butyl?

Fluazifop-P-butyl is a post-emergent herbicide that is used to control grass weeds in broadleaf crops and ornamentals. It acts by inhibiting fatty acid synthesis in the plant.

Health Considerations

Can Approved Uses of Fluazifop-P-butyl Affect Human Health?

Fluazifop-P-butyl is unlikely to affect your health when used according to the revised label directions.

People could be exposed to fluazifop-P-butyl through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The PMRA concluded that fluazifop-P-butyl is unlikely to affect human health provided that the proposed mitigation measures are implemented.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

Fluazifop-P-butyl is currently registered in Canada for use on canola, creeping red fescue, flax, lentils, mustard, peas (field), soybeans, sugar beets, sunflowers, tobacco, ginseng, alfalfa, red clover and birdsfoot trefoil, asparagus, broccoli, Brussels sprouts, cabbage, cauliflower, carrots, cucumber, onions, potatoes, rutabagas, lupins (sweet white), tomatoes, apples, pears, peaches, cherries (sweet and sour), apricots, plums, blueberries, non-bearing cranberries, strawberries, raspberries, grapes and plant shrub, tree, forest and ornamental nurseries. Fluazifop-P-butyl may be used on other crops in other countries that are imported into Canada.

In Canada, MRLs have been established for apricots, nectarines, peaches, plumcots, plums, prune plums, sweet cherries, tart cherries, soybeans, strawberries, mustard, flax, solin, blueberries, grapes, milk, eggs, meat, meat-byproducts and animal fat. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

Environmental Considerations

What Happens When Fluazifop-P-butyl Is Introduced Into the Environment?

Fluazifop-P-butyl is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target aquatic organisms and terrestrial plants could be exposed to fluazifop-P-butyl in the environment. The PMRA concluded that the continued registration of fluazifop-P-butyl is acceptable provided that the proposed mitigation measures to further protect the environment are implemented. The PMRA proposes aquatic and terrestrial buffer zones for fluazifop-P-butyl to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include mitigation measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of fluazifop-P-butyl, the PMRA is requiring further mitigation measures for product labels.

Human Health

- Improvements to the personal protective equipment label statements.
- Hazard label statement regarding the sensitization potential.
- Prohibition of fluazifop-P-butyl use in greenhouses.
- A 12-hour restricted-entry interval to protect workers re-entering treated sites.

Environment

- Additional hazard label statements for risk to aquatic species.
- Additional advisory label statements to reduce potential surface and groundwater contamination.
- Buffer zones to protect non-target aquatic and terrestrial habitats.

Appendix II lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on fluazifop-P-butyl within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

3 As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Expansion of use-pattern since publication of the PRVD

1.1 Comment

Venture L Herbicide (Reg. No. 21209) was registered for use on dry edible beans on May 13, 2011 with a proposed MRL of 0.15 ppm. This new use should be included in the final re-evaluation decision for fluazifop-P-butyl.

PMRA Response

The use on dry edible beans was registered after the scientific evaluation of fluazifop-P-butyl was completed. This use was not considered during the re-evaluation, and therefore is not included in the final re-evaluation decision. The directions for use on dry edible beans are, however, consistent with the re-evaluation outcome.

2.0 Model input data for aquatic buffer zones

2.1 Comment

The toxicity endpoints for rainbow trout, *Oncorhynchus mykiss,* and the saltwater shrimp *Mysidopsis bahia,* selected by the PMRA for the calculation of aquatic buffer zones were based on the end-use product Fusilade II 125EC (Table 2, Appendix IV, PRVD2011-11). Available toxicity data for the active ingredient, rather than data for an end-use product, should be used in risk assessments. The following toxicity data are available for fluazifop-P-butyl for aquatic species: LC_{50}s of 1.41 mg a.i./L and 0.54 mg a.i./L for rainbow trout and for *Mysidopsis bahia*, respectively.

PMRA Response

The toxicity endpoints used in the risk assessment, and consequently used by the PMRA for the purpose of calculating buffer zones, are generally the most sensitive toxicity endpoint available. For the calculation of the buffer zones for fluazifop-P-butyl (PRVD2011-11), the PMRA selected a $^1/_{10}$ LC_{50} = 0.055 mg/L for the most sensitive freshwater species (based on an LC_{50} of 0.55 mg/L in rainbow trout; Agriculture Canada Decision Document E88-01 for fluazifop-P-butyl, June 27, 1988) and a ½ LC_{50} of 0.27 mg/L for the most sensitive estuarine/marine species (based on an LC_{50} of 0.54 mg/L for *Mysidopsis bahia*; European Food Safety Authority Draft Assessment Report, September, 2007 (PMRA#2157298)).

While the LC_{50} of 1.41 mg/L in the freshwater rainbow trout (European Food Safety Authority Draft Assessment Report, September, 2007 (PMRA#2157298)) is a valid endpoint for this species, it is considered less conservative than the value used in the PMRA assessment.

Appendix II Label Amendments for Products Containing Fluazifop-P-butyl

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included on the primary display panel of the label.

POTENTIAL SKIN SENSITIZER

II) The following statements must be included in a section entitled **PRECAUTIONS**.

May be harmful if absorbed through skin. Avoid contact with skin and clothing. Potential skin sensitizer.

Wear coveralls over long-sleeved shirt and long pants, chemical resistant gloves, socks and chemical resistant footwear during mixing, loading, application, clean-up and repair. Wear goggles or face shield during mixing/loading.

DO NOT enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

DO NOT use in greenhouses.

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:		
		Aquatic Habitat of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	
Field sprayer[a]	Ginseng	1	0	5
	All other crops	1	0	2

[a] For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

IV) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

This product contains an active ingredient and aromatic petroleum distillates which are toxic to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.
Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

References

A. Studies/Information Provided by the Applicant/Registrant-Unpublished

Studies Considered in the Chemistry Assessment

PMRA Document Number: 1242274
Reference: 2004, Chemical and Physical Properties Summary Ingredient, (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.14.1,2.14.10,2.14.11,2.14.12, 2.14.13, 2.14.14, 2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9

PMRA Document Number: 1242275
Reference: 1999, Fluazifop-p-Butyl: Physical and Chemical Properties of Pure Material, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14, 2.14.2, 2.14.3, 2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9

PMRA Document Number: 1242276
Reference: Fluazifop-p-Butyl (TGAI): Determination of Physical and Chemical Properties SPL Project Number: 1292/004,
DACO:2.14.1,2.14.10,2.14.12,2.14.13,2.14.14, 2.14.2, 2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9

PMRA Document Number: 1242277
Reference: 2004, Discussion of Impurities of Toxicological Concern Ingredient (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.13.4

PMRA Document Number: 1242278
Reference: Fluazifop-p-Butyl : Detailed Analysis of Technical Materials Representative of Large Scale Production, DACO: 2.13.3

PMRA Document Number: 1242279
Reference: 2003, Fluazifop-p-Butyl : Mass Spectra Library of Fluazifop-p-Butyl and Associated Compunds, DACO: 2.13.2

PMRA Document Number: 1242280
Reference: The Determination of Enantiomer Ratio in Fluazifop-p-Butyl Technical Material by High Performance Liquid Chromatography, DACO: 2.13.2

PMRA Document Number: 1242281
Reference: The Determination of Fluazifop-Butyl and Associated Impurities in Fluazifop-p-Butyl Technical Material By Capillary Gas Chromatography, DACO: 2.13.2

PMRA Document Number: 1242282
Reference: The Determination of Polar Fluazifop-p-Butyl Associated Impurities in Technical Material by High Performance Liquid Chromatography, DACO: 2.13.2

PMRAPMRA Document Number: 1242283
Reference: Method Validation:AMP 10083-01B/VAL-01 the Determination of Fluazifop-p-Butyl Technical Material by Capillary Gas Chromatography, DACO: 2.13.1

PMRA Document Number: 1242284
Reference: Method Validation:AMP 10084-01A/VAL-01 the Determination of Enantiomer Ratio in Fluazifop-p-Butyl Technical Materials by High Preformance Liquid Chromatography, DACO: 2.13.1

PMRA Document Number: 1242285
Reference: Method Validation:AMP 10085-01B/VAL-01 the Determination of Polar Fluazifop-p-Butyl Associated Impurities in Technical Materials by High Performance Liquid Chromatography, DACO: 2.13.1

PMRA Document Number: 1242286
Reference: Establishing Certified Limits Ingredient (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.12.1

PMRAPMRA Document Number: 1242287
Reference: Discussion of Formation Impurities (Confidential Cross Reference 4), DACO: 2.11.4

PMRAPMRA Document Number: 1242288
Reference: Description of Product Process (Confidential Cross Reference 3), DACO: 2.11.3
PMRA Document Number: 1242289
Reference: Description of Materials Used to Produce the Product List of Starting Materials (Confidential Cross Reference 2), DACO: 2.11.2

PMRAPMRA Document Number: 1242290
Reference: Manufacturing Process PP 5 (ASF 615), Fluazifop-p-Butyl, DACO: 2.11.1

PMRAPMRA Document Number: 1242291
Reference: 2004, Chemistry Requirements for the Registration of a Technical Grade Active Ingredient (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9

B. Additional Information Considered - Published Information

Information Considered in the Canadian Water Monitoring Assessment

Published Information

PMRA Document Number: 1311118
Reference: Anderson, A. 2005. Overview of pesticide data in Alberta surface waters since 1995. ISBN: 0-7785-3931-8 (Printed Edition), 0-7785-3933-4 (On-Line Edition). Alberta Environment, Environmental Monitoring and Evaluation Branch. Edmonton, Alberta. http://www3.gov.ab.ca/env/info/infocentre/publist.cfm DACO 8.6

PMRA Document Number: 1560632
Reference: 2003. Pesticide Sampling Program for Selected Municipal Drinking Water Supplies in New Brunswick: Tables 4-6: Results by Municipality and QA/QC Samples. DACO 8.6

PMRA Document Number: 1640595
Reference: Boldon, M. and Harty, C. 2003. Pesticide Sampling Program for Selected Municipal Drinking Water Supplies in New Brunswick. Pesticides Management Unit, New Brunswick Environment. DACO 8.6

PMRA Document Number: 1311124
Reference: Byrtus, G., Anderson, A-M., and Saffran, K. 2002. Determination of New Pesticides in Alberta's Surface Waters (1999-2000). Prepared for The Water Research User Gro up, Alberta Environment. DACO: 8.6

PMRA Document Number: 1311142
Reference: Byrtus, G., K. Pongar, C. Browning, R. Burland, E. McGuinness, and D. Humphries. 2004. A summary of pesticide residues from the Alberta treated water survey, 1995-2003. Alberta Environment, Environmental Assurance Service. Edmonton. 57 pp DACO: 8.6.

PMRA Document Number: 1739314
Reference: Harris, K.A, N. Dangerfield, M. Woudneh, T. Brown, S. Verrin, and P.S. Ross. 2008. Partitioning of current-use and legacy pesticides in salmon habitat in British Columbia, Canada. Environmental Toxicology and Chemistry 27(11):2253-2262. DACO: 8.6.

PMRA Document Number: 2157298
Reference: European Commission, 2007, Draft Assessment Report (DAR) - Public Version - Initial Risk Assessment Provided by the Rapporteur Member State France for the Existing Active Substance Fluazifop-P-Butyl of the third stage (Part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC Volume 1. DACO 12.5

C. Additional Information Considered - Unpublished Information

Additional Unpublished Information Considered in the Health Assessment- Exposure

Unpublished Information

PMRA Document Number: 2028140
Reference: 2005, Dietary (Food and Water) Exposure Assessment (DEA) Using DEEM FCID, DACO 7.4